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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,235	12/18/2001	Michael A. Murphy	1865.1-4	9798

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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,235

Applicant(s)

MURPHY ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 14-17, 25, 29, 38, 44-61 and 65-107 is/are pending in the application.

4a) Of the above claim(s) 4-9, 14-17, 25, 29, 38, 44-61, 66-73, 79-89, 96 and 98-105 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 65, 74-78, 90-95, 97 and 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 2-9, 14-17, 25, 29, 38, 44-61, 65-107 are pending. Claims 4-9, 14-17, 25, 29, 38, 44-61, 66-73, 79-89, 96, 98-105, 107 are withdrawn from consideration. (Claim 96 had previously been indicated as directed to an elected species, but in fact, is directed to a non-elected species.) The elected polyamine is the macrocyclic polyamine of claim 3 with $R1-R4 = -(CH_2CH_2)_n$ with $n=3-6$ and the elected disease is diabetes.

Claims 2, 3, 65, 74-78, 90-95, 97, 106 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicants claim a treatment of diabetes but provide no experimental evidence of efficacy, but rather a discussion of the literature on pages 14-21 and a recitation of merely hypothetical benefits to the treatment on pages 62-65. Applicants point to experimental data in US patent 5,906,996, however, that data concerns the non-elected Parkinson's disease. In particular, no tests on animal models to demonstrate effectiveness in humans is provided. Absent a demonstration, one of ordinary skill would not find the claimed treatment credible on its face, given the uncertainty of the fate of the claimed compounds in vivo.

Claims 2, 3, 65, 74-78, 90-95, 97, 106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because the claimed invention lacks patentable utility, the specification cannot be enabled for the elected treatment. Further, applicants provide no modality for treatment. That is, it is unclear as to how and where the treatment is to be delivered. With regard to the Wands factors: The nature of the

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invention is complex in view of the many parameters influencing the onset of diabetes, as disclosed on pages 14-21, therefore, the burden upon one of ordinary skill to determine an efficacious treatment will be high. The breadth of the claims is wide in view of the many different aspects of polyamine treatment disclosed on pages 62-65. The guidance of the specification is minimal; there is no suggestion of loci of treatment, delivery vehicles, nor dosage regimens. There are no working examples directed to the claimed treatment. The state of the art regarding diabetes treatment is low given that there is no cure known for the disease. Given the low state of the art and the plethora of parameters affecting the onset the disease, the predictability of the art is low, thus, one of ordinary skill would not routinely determine the parameters of efficacious treatment. Because the determination of a efficacious treatment parameters is not routine, the amount of experimentation necessary will be high.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



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